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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE:	:	
Fosamax Products Liability Litigation	:	1:06-md-1789 (JFK)
	:	
This Document Relates to:	:	**ANSWER AND AFFIRMATIVE**
Carol Fasolino	:	**DEFENSES OF MERCK**
v. Merck & Co., Inc.	:	**& CO., INC.;**
	:	**DEMAND FOR JURY TRIAL**
Case No: 1:07-cv-9881-JFK	:	

Defendant, Merck Co., Inc. ("Merck"), by and through its undersigned attorneys, hereby answers the Complaint. Merck denies all allegations set forth in the Complaint except to the extent such allegations are specifically admitted below:

PARTIES - PLAINTIFF

1. Merck is without knowledge as to the allegations of Paragraph 1.

DEFENDANT

2. Merck denies each and every allegation of Paragraph 2, except that it admits that Merck is a New Jersey Corporation with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey.

3. Merck admits that it is registered to do business in the State of New York.

4. Merck denies each and every allegation of Paragraph 4, except that Merck admits that it manufactured, marketed and distributed the prescription medicine FOSAMAX® and that FOSAMAX® is a prescription medication approved by the Federal Food and Drug Administration ("FDA") for prescription in accordance with its approved prescribing information.

JURISDICTION

5. The allegations contained in Paragraph 5 are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph, except that for jurisdictional purposes only, admits that the amount in controversy exceeds $75,000.00.

FACTS

6. Merck denies each and every allegation of Paragraph 6, except that it admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX®, that FOSAMAX® is Merck's trade name for alendronate sodium, and that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck respectfully refers the Court to the Physicians' Desk Reference ("PDR") for FOSAMAX® for its actual language and full text.

7. Merck denies each and every allegation of Paragraph 7, except that Merck admits that it sought and received FDA approval to manufacture and market the prescription medicine FOSAMAX® and respectfully refers the Court to its prescribing information for FOSAMAX® for its indicated uses.

8. Merck denies each and every allegation of Paragraph 8.

9. Merck denies each and every allegation of Paragraph 9.

10. Merck denies the allegations of Paragraph 10, except to state that it is without knowledge as to whether Plaintiff took FOSAMAX®.

11. Merck denies the allegations of Paragraph 11, except to state that it is without knowledge as to whether Plaintiff took FOSAMAX®.

12. Merck denies each and every allegation of Paragraph 12, except that Merck admits that on January 31, 2005, it received a request dated January 24, 2005 from the FDA to update the label for FOSAMAX® to include bisphosphonate class labeling for ONJ. Merck submitted a draft revised label to the FDA on March 1, 2005. FDA comments on this draft revised label were received in June 2005, and the new label was made publicly available in July 2005.

13. Merck denies each and every allegation of Paragraph 13.

14. Merck is without knowledge as to the allegations of Paragraph 14. Should a further response be deemed necessary, Merck denies each and every allegation of Paragraph 14.

15. Merck denies the allegations of Paragraph 15, except to state that it is without knowledge as to whether Plaintiff ingested FOSAMAX®.

COUNT I

PRODUCTS LIABILITY – DEFECTIVE DESIGN

16. Merck repleads its answers to Paragraphs 1 through and including 15, and by this reference, hereby incorporates the same herein in this paragraph and makes the same as part hereof, as though fully set forth *verbatim*.

17. Merck denies each and every allegation of Paragraph 17, except that it admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

18. Merck denies each and every allegation of Paragraph 18.

19. Merck denies each and every allegation of Paragraph 19, except that it admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information and states that it is without knowledge as to the condition of the FOSAMAX® Plaintiff alleges she consumed.

20. Merck denies the allegations of Paragraph 20, except to state that it is without knowledge as to whether Plaintiff took, received or consumed FOSAMAX®, the manner in which Plaintiff utilized FOSAMAX®, and the extent of Plaintiff's knowledge concerning FOSAMAX®. Merck further avers that the FDA approved FOSAMAX® as safe and effective for its intended uses subject to the information contained in its prescribing information.

21. The allegations contained in Paragraph 21 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, each and every allegation of Paragraph 21 is denied.

22. Merck denies each and every allegation of Paragraph 22, except that it admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

23. Merck denies each and every allegation of Paragraph 23.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck its reasonable attorney's fees, together with such other and further relief that the Court may deem just and proper.

COUNT II

PRODUCTS LIABILITY – FAILURE TO WARN

24. Merck repleads its answers to Paragraphs 1 through and including 23, and by this reference, hereby incorporates the same herein in this paragraph, and makes the same as part hereof, as though fully set forth *verbatim*.

25. Merck denies each and every such allegation of Paragraph 25, except that Merck admits that it manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

26. Merck denies each and every allegation of Paragraph 26 and avers that the FDA approved FOSAMAX® as safe and effective for its intended uses subject to the information contained in its prescribing information.

27. Merck denies each and every allegation of Paragraph 27 and avers that the FDA approved FOSAMAX® as safe and effective for its intended uses subject to the information contained in its prescribing information.

28. Merck denies each and every allegation of Paragraph 28 and avers that the FDA approved FOSAMAX® as safe and effective for its intended uses subject to the information contained in its prescribing information.

29. Merck denies each and every allegation of Paragraph 29 and avers that the FDA approved FOSAMAX® as safe and effective for its intended uses subject to the information contained in its prescribing information.

30. Merck denies each and every allegation of Paragraph 30 and avers that the FDA approved FOSAMAX® as safe and effective for its intended uses subject to the information contained in its prescribing information.

31. Merck denies each and every allegation of Paragraph 31.

32. Merck denies each and every allegation of Paragraph 32, except that Merck admits that it manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information and avers that the FDA approved FOSAMAX® as safe and effective for its intended uses subject to the information contained in its prescribing information.

33. Merck denies each and every allegation of Paragraph 33.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck its reasonable attorney's fees, together with such other and further relief that the Court may deem just and proper.

COUNT III

PRODUCTS LIABILITY – FAILURE TO WARN

34. Merck repleads its answers to Paragraphs 1 through and including 33, and by this reference, hereby incorporates the same herein in this paragraph, and makes the same as part hereof, as though fully set forth *verbatim*.

35. Merck repleads its answers to Paragraphs 1 through and including 34, and by this reference, hereby incorporates the same herein in this paragraph, and makes the same as part hereof, as though fully set forth *verbatim*.

36. Merck denies each and every allegation of Paragraph 36, except that Merck admits that it manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

37. Merck denies each and every allegation of Paragraph 37 and avers that the FDA approved FOSAMAX® as safe and effective for its intended uses subject to the information contained in its prescribing information.

38. Merck denies each and every allegation of Paragraph 38 and avers that the FDA approved FOSAMAX® as safe and effective for its intended uses subject to the information contained in its prescribing information.

39. Merck denies each and every allegation of Paragraph 39.

40. Merck denies each and every allegation of Paragraph 40.

41. Merck denies each and every allegation of Paragraph 41.

42. Merck denies the allegations of Paragraph 42, except to state that it is without knowledge as to whether Plaintiff was prescribed or provided FOSAMAX® and by whom or whether she consumed FOSAMAX® and as to the reasons for her alleged consumption of FOSAMAX®.

43. The allegations contained in Paragraph 43 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, each and every allegation of Paragraph 43 is denied.

44. Merck denies each and every allegation of Paragraph 44 and avers that the FDA approved FOSAMAX® as safe and effective for its intended uses subject to the information contained in its prescribing information.

45. Merck denies each and every allegation of Paragraph 45.

46. Merck denies each and every allegation of Paragraph 46 and avers that the FDA approved FOSAMAX® as safe and effective for its intended uses subject to the information contained in its prescribing information.

47. Merck denies each and every allegation of Paragraph 47.

48. Merck denies each and every allegation of Paragraph 48.

49. The allegations of Paragraph 49 are conclusions of law to which no response is required; to the extent that a response deemed necessary, each and every allegation of Paragraph 49 is denied.

50. Merck denies each and every allegation of Paragraph 50.

51. Merck denies the allegations of Paragraph 51, except to state that it is without knowledge as to whether Plaintiff purchased or consumed FOSAMAX®.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck its reasonable attorney's fees, together with such other and further relief that the Court may deem just and proper.

COUNT IV

BREACH OF EXPRESS WARRANTY

52. Merck repleads its answers to Paragraphs 1 through and including 51, and by this reference, hereby incorporates the same herein in this paragraph, and makes the same as part hereof, as though fully set forth *verbatim*.

53. Merck denies each and every allegation of Paragraph 53, except that Merck admits that it manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

54. The allegations in Paragraph 54 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, each and every allegation of Paragraph 54 is denied, and Merck avers that the FDA approved FOSAMAX® as safe and effective for its intended uses subject to the information contained in its prescribing information.

55. Merck is without knowledge as to the allegations of Paragraph 55. Should a further response be deemed necessary, Merck denies each and every allegation of Paragraph 55.

56. Merck denies the allegations of Paragraph 56, except that Merck admits that it manufactured, marketed and distributed FOSAMAX® for prescription in accordance with its approved prescribing information and further states that it is without knowledge as to the allegations of Paragraph 56 concerning the knowledge of Plaintiff and/or her prescribing physician concerning FOSAMAX®.

57. The allegations contained in Paragraph 57 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, each and every allegation of Paragraph 57 is denied. In addition, Merck avers that the FDA approved FOSAMAX® as safe and effective for its intended uses subject to the information contained in its prescribing information and further avers that it has not breached any duty under applicable law.

58. The allegations contained in Paragraph 58 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, each and every allegation of Paragraph 58 is denied. Merck further avers that the FDA approved

FOSAMAX® as safe and effective for its intended uses subject to the information contained in its prescribing information.

59. Merck denies each and every allegation of Paragraph 59 and avers that the FDA approved FOSAMAX® as safe and effective for its intended uses subject to the information contained in its prescribing information.

60. Merck denies each and every allegation of Paragraph 60.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck its reasonable attorney's fees, together with such other and further relief that the Court may deem just and proper.

COUNT V

PUNITIVE DAMAGES

61. Merck repleads its answers to Paragraphs 1 through and including 60 and by this reference, hereby incorporates the same herein in this paragraph, and makes the same as part hereof, as though fully set forth *verbatim*.

62. Merck denies each and every allegation of Paragraph 62.

63. Merck denies each and every allegation of Paragraph 63.

64. Merck denies each and every allegation of Paragraph 64.

65. Merck denies each and every allegation of Paragraph 65.

66. Merck denies each and every allegation of Paragraph 66.

67. Merck denies each and every allegation of Paragraph 67.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck its reasonable attorney's fees, together with such other and further relief that the Court may deem just and proper.

RELIEF REQUESTED

Merck denies that Plaintiff is entitled to any of the relief requested.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck its reasonable attorney's fees, together with such other and further relief that the Court may deem just and proper.

AFFIRMATIVE DEFENSES

Discovery and investigation may reveal that any one or more of the following affirmative defenses should be available to Merck in this matter. Merck, therefore, asserts said affirmative defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Merck may withdraw any of these affirmative defenses as may be appropriate. Further, Merck reserves the right to amend its Answer to assert additional defenses, cross-claims, counterclaims, and other claims and defenses as discovery proceeds. Further answering and by way of additional defense, Merck states as follows:

FIRST AFFIRMATIVE DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations and is otherwise untimely.

SECOND AFFIRMATIVE DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

THIRD AFFIRMATIVE DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

FOURTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening cause or causes.

FIFTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff asserts claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

SIXTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff asserts claims based upon an alleged failure by Merck to warn Plaintiff directly of alleged dangers associated with the use of FOSAMAX®, such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to the prescribing physician.

SEVENTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were caused in whole or in part by the contributory negligence of the allegedly injured Plaintiff.

EIGHTH AFFIRMATIVE DEFENSE

Any liability that might otherwise be imposed upon this Defendant is subject to reduction by the application of the doctrine of comparative fault and/or negligence.

NINTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were only sustained after Plaintiff knowingly, voluntarily, and willfully

assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any medicine or pharmaceutical preparation manufactured or distributed by Merck or other manufacturer.

TENTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

ELEVENTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiff's misuse or abuse of FOSAMAX®.

TWELFTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, idiosyncratic reactions, subsequent medical conditions or natural courses of conditions for which this Defendant is not responsible.

THIRTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff relies upon any theory of breach of warranty, such claims are also barred for lack of timely notice of breach and/or lack of privity.

FOURTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part under the applicable state law because FOSAMAX® was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

SIXTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused the injuries asserted in the Complaint, such an award would, if granted, violate Merck's state and federal constitutional rights.

SEVENTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff seeks punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

EIGHTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff seeks punitive damages, such claim is barred because FOSAMAX® and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

NINETEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

TWENTIETH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part because Merck provided legally adequate "directions or warnings" as to the use of FOSAMAX® and any other medicine or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

TWENTY-FIRST AFFIRMATIVE DEFENSE

Plaintiff's claims are barred under Section 4, *et seq.*, of the Restatement (Third) of Torts: Products Liability.

TWENTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff's claims are barred under comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

TWENTY-THIRD AFFIRMATIVE DEFENSE

There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of FOSAMAX®.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part by failure to mitigate damages.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part because Merck's conduct conforms with medical knowledge.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

With respect to each and every cause of action, Plaintiff is not entitled to recovery for strict liability because Plaintiff cannot state claims founded in strict liability because,

among other things, comments j and k to Section 402A of the Restatement (Second) of Torts relegates Plaintiff's claims to a negligence cause of action.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

All activities of Merck as alleged in the Complaint were expressly authorized and/or regulated by a government agency. Therefore, Plaintiff's claims pertaining to unfair or deceptive practices are barred.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

With respect to each and every cause of action, Plaintiff is not entitled to recover because if the product involved was unsafe, which Merck denies, then it was unavoidably unsafe as defined in Restatement of Torts. The apparent benefits of the product exceeded any apparent risk given the scientific knowledge available when the product was marketed.

TWENTY-NINTH AFFIRMATIVE DEFENSE

Merck's advertisements and labeling with respect to the products which are the subject matter of this action were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States and New York Constitutions.

THIRTIETH AFFIRMATIVE DEFENSE

The public interest in the benefit and availability of the product which is the subject matter of this action precludes liability for risks, if any, resulting from any activities undertaken by Defendant, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiff's

claims, if it is determined there is a risk inherent in the product which is the subject matter of this action, then such risk, if any, is outweighed by the benefit of the product.

THIRTY-FIRST AFFIRMATIVE DEFENSE

At all times relevant herein, any product which is the subject matter of this action manufactured and distributed by Merck in any state in the United States was manufactured and distributed in a reasonable and prudent manner based upon available medical and scientific knowledge and further was processed and distributed in accordance with and pursuant to all applicable regulations of the FDA.

THIRTY-SECOND AFFIRMATIVE DEFENSE

With respect to each and every purported cause of action, the acts of Merck were at all times done in good faith and without malice.

THIRTY-THIRD AFFIRMATIVE DEFENSE

To the extent there were any risks associated with the use of the product which is the subject matter of this action which Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and state law.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff has not sustained an ascertainable loss of property or money.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiff has not suffered any actual injury or damages.

THIRTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiff’s claims are barred under the doctrine of economic loss.

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

This case is more appropriately brought in a different venue as defined in 28 U.S.C. §1404(a).

THIRTY-EIGHTH AFFIRMATIVE DEFENSE

This case is subject to dismissal and/or transfer to another venue pursuant to 28 U.S.C. §1406(a).

THIRTY-NINTH AFFIRMATIVE DEFENSE

This case is subject to dismissal or stay on the grounds of *forum non conveniens.*

FORTIETH AFFIRMATIVE DEFENSE

Plaintiff's claims of fraud are not pleaded with the required particularity.

FORTY-FIRST AFFIRMATIVE DEFENSE

Plaintiff cannot recover for the claims asserted because Plaintiff has failed to comply with the conditions precedent necessary to bring this action and/or each particular cause of action asserted by Plaintiff.

FORTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff's claims for breach of warranty are barred because Plaintiff did not rely on such warranties and the claims are otherwise barred for lack of timely notice, lack of privity and/or because the alleged warranties were disclaimed.

FORTY-THIRD AFFIRMATIVE DEFENSE

An asymptomatic plaintiff lacks standing because she has suffered no damages and no injury-in-fact.

FORTY-FOURTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff asserts claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products, FDA Docket No. 2000N-1269 (January 24, 2006).

FORTY-FIFTH AFFIRMATIVE DEFENSE

The substantive law of New York applies to Plaintiff's claims.

Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Merck to determine all of its legal, contractual and equitable rights, Merck reserves the right to amend and/or supplement the averments of its Answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery.

Merck will rely on all defenses that may become available during discovery or trial.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

JURY DEMAND

Merck demands a trial by jury as to all issues so triable.

DATED: New York, New York
December 18, 2007

Respectfully submitted,

HUGHES HUBBARD & REED LLP

By: /s/
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